UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JEANNINE JANET RIVERS,

Plaintiff,

v. **Case No. 19-CV-988**

B BRAUN INTERVENTIONAL SYSTEMS INC, et al.,

Defendants.

DECISION AND ORDER

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1. Background

Jeannine Janet Rivers was 49 years old and morbidly obese when she underwent gastric bypass surgery on July 12, 2011. (ECF No. 77-2, ¶¶ 69-70.) In part because she had suffered a pulmonary embolism in 2006 (ECF No. 77-2, ¶ 69), her bariatric surgeon ordered the placement of an inferior vena cava (IVC) filter (ECF No. 77-2, ¶ 71) in preparation for the gastric bypass surgery. The filter is placed in the inferior vena cava, the largest human vein (ECF No. 77-2, ¶ 1), and is intended to capture a blood clot before it can reach the patient's heart or lungs and cause potentially fatal complications (ECF No. 77-2, ¶¶ 4, 7). The surgeon did not specify what kind of filter should be placed (ECF No. 77-2, ¶ 73), and the implanting physician used a Braun VenaTech LP filter

(ECF No. 76, ¶ 1), although he does not recall if he chose that filter or if that was the only type of filter available at the hospital (ECF No. 77-2, ¶ 84).

The physician implanted the filter without any problem and Rivers underwent gastric bypass surgery the same day. (ECF No. 77-2, ¶¶ 81-82.) Rivers was discharged from the hospital two days later. (ECF No. 77-2, ¶ 82.)

A couple of weeks later, on July 29, 2011, Rivers went to the emergency room complaining of leg pain. (ECF No. 77-2, ¶ 92.) An ultrasound ruled out a blood clot. (ECF No. 77-2, ¶ 92.) On July 31, 2011, Rivers again went to the emergency room, this time complaining of chest pain after passing out. (ECF No. 77-2, ¶ 93.) Rivers underwent a CT scan and a radiologist identified multiple pulmonary emboli. (ECF No. 77-2, ¶ 94.) However, the radiologist did not recognize that the CT scan showed that the filter had migrated to the right atrium of Rivers's heart. (ECF No. 77-2, ¶ 94.) Rivers was admitted to the hospital, treated for the blood clots, and discharged on August 3, 2011. (ECF No. 77-2, ¶ 96.)

Rivers continued to complain of palpitations, and an X-ray on August 8, 2011, again did not lead to identification of the migrated filter in Rivers's heart. (ECF No. 77-2, ¶ 97.) Likewise, the filter was not identified following a CT scan on August 17, 2011, after Rivers continued to complain of shortness of breath and chest pain. (ECF No. 77-2, ¶¶ 98-99.) The radiology report following another CT scan over two years later, on December 23, 2013, stated that the filter "appears normal." (ECF No. 77-2, ¶ 100.) A

chest X-ray on February 17, 2014, and a February 18, 2014, echocardiogram and cardiac catheterization did not mention the filter. (ECF No. 77-2, ¶¶ 101, 103.) Nor was the filter identified in a November 19, 2014, CT scan. (ECF No. 77-2 at 105.)

It was not until July 20, 2016, five years after the filter was implanted, that an echocardiogram finally recognized that the filter had migrated to Rivers's heart. (ECF No. 77-2, ¶ 106.) Two days later Rivers underwent open-heart surgery to remove the filter, a procedure that also required the replacement of her tricuspid valve. (ECF No. 77-2, ¶ 107.) Rivers suffered an infection following the surgery, which required treatment. (ECF No. 77-2, ¶ 112.)

On July 11, 2019, Rivers brought this action against B Braun Interventional Systems, Inc. and B Braun Medical. Because the defendants are indistinct for present purposes, the court refers to B Braun Interventional Systems, Inc. and B Braun Medical together in the singular as Braun.

Rivers brought claims for negligence, strict products liability – failure to warn, strict products liability – design defect, strict products liability – manufacturing defect, breach of the implied warranty of merchantability, and negligent misrepresentation. (ECF No. 1 at 12-23.) She also presented a seventh cause of action for punitive damages (ECF No. 1 at 24), but punitive damages are a remedy, not a claim, *Estate of Wobschall v. Ross*, 488 F. Supp. 3d 737, 755 (E.D. Wis. 2020). Rivers subsequently withdrew her claims for manufacturing defect and breach of implied warranty. (ECF No. 77-1 at 7.)

All parties have consented to the full jurisdiction of this court pursuant to 28 U.S.C. § 636(c). (ECF Nos. 3, 11, 18.) The court has subject matter jurisdiction based on the diversity of the citizenship of the parties under 28 U.S.C. § 1332(a)(1).

Before the court are a plethora of pretrial motions supported by extensive and often repetitive filings spanning more than 12,000 pages. Navigation of these filings has been burdened by the parties' disorganization, failure to fully comply with the court's electronic filing policies, and a seeming overuse of redactions[1] (thereby requiring the filing of both a redacted and unredacted version of the same document). Rivers seeks partial summary judgment. (ECF No. 56.) Braun seeks summary judgment (ECF No. 65) and to exclude six experts (ECF Nos. 57, 59, 60, 61, 62, 63).

2. Request for Oral Argument

The parties have written "Oral Argument Requested" in the caption of nearly all of their filings related to the present motions. But at no point do they explain why they believe oral argument is necessary or would be helpful. The parties having failed to demonstrate that oral argument is necessary, the request is denied.

[1] If redactions are truly necessary, parties are expected to take care to make sure that their redactions are effective. Highlighting digital text in black is not a proper redaction. Such efforts are easily bypassed and serve only to bring attention to the information the party wants to keep confidential.

3. Motions Regarding Experts

3.1. Applicable Law

The admissibility of expert opinions is governed by Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *Kirk v. Clark Equip. Co.*, 991 F.3d 865, 871 (7th Cir. 2021). Under Rule 702 the court acts as a gatekeeper to ensure that proffered expert testimony "is not only relevant, but reliable." *Id.* at 872 (quoting *Daubert*, 509 U.S. at 589). "In performing this role, the district court must engage in a three-step analysis, evaluating: '(1) the proffered expert's qualifications; (2) the reliability of the expert's methodology; and (3) the relevance of the expert's testimony.'" *Id.* (quoting *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 779 (7th Cir. 2017)).

The fact that an expert is qualified to give an opinion is not by itself a sufficient basis for admissibility. *Kirk*, 991 F.3d at 873. In assessing the reliability of an expert opinion, courts may consider the following non-exhaustive factors:

> (1) Whether the particular scientific theory can be (and has been) tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; and (5) whether the technique has achieved general acceptance in the relevant scientific or expert community.

Id. (quoting *Deputy v. Lehman Bros., Inc.*, 345 F.3d 494, 505 (7th Cir. 2003)) (internal brackets and quotation marks omitted); *see also Gopalratnam*, 877 F.3d at 779-80

(discussing additional factors outlined in the Notes of Advisory Committee on Rules to the 2000 Amendment of Rule 702).

Because there are many different kinds of experts and expertise, the test for reliability is flexible, and no one factor is dispositive. *Kirk*, 991 F.3d at 873; *Gopalratnam*, 877 F.3d at 780. Courts must be mindful that they are not assessing the correctness of the expert's opinion but merely the soundness of the expert's methods. *Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."); *Kirk*, 991 F.3d at 873; *Kopplin v. Wis. Cent. Ltd.*, 914 F.3d 1099, 1104 (7th Cir. 2019) ("The focus is on the expert's methodology, not his ultimate conclusions."). "The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or where appropriate, on summary judgment." *Gopalratnam*, 877 F.3d at 781 (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000); citing *Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806 (7th Cir. 2013)).

3.2. Derek Muehrcke

Derek Muehrcke is a cardiothoracic surgeon with decades of experience implanting and removing filters like the one at issue here. Retained by the plaintiff as an expert, he produced a report that contains 24 separately numbered opinions (some of which contain multiple opinions). (ECF No. 63-3 at 15-24.)

3.2.1. Muehrcke's Opinions

In broad terms, Muehrcke opines that various symptoms, treatments, and complications that Rivers experienced were caused by the migration of the filter. (ECF No. 63-3 at 15-16, opinions 2, 3, 4, 5, 7, and 8.) It is very unlikely that the laparoscopic gastric bypass surgery caused the filter to migrate. (ECF No. 63-3 at 15, opinion 1.) Rivers would have needed open-heart surgery even if the migration had been recognized at the first opportunity. (ECF No. 63-3 at 17, opinion 9.) Rivers will need a valve transplant—and thus open-heart surgery—again. (ECF No. 63-3 at 16, opinion 6.)

Muehrcke says that Braun manufactured a filter that had a lower migration rate and, although Braun knew that this other filter was safer, it chose to sell that filter only outside the United States and to sell in the United States the "bad" filter that Rivers received. (ECF No. 63-3 at 17, 18, 20, 24, opinions 10, 11, 12, 15, 16, 17, 18, 24.)

Braun insufficiently tested its filter (ECF No. 63-3 at 23, opinions 21, 22) and misleadingly stated that its filter had been cleared by the FDA as safe and effective (ECF No. 63-3 at 23, opinion 21). Braun underestimated the rate at which its filters migrated and inaccurately reported Rivers's migration to the FDA. (ECF No. 63-3 at 21-22, opinions 19, 20.)

According to Muehrcke, an implanting physician would expect a medical device manufacturer to provide certain information, such as the results of safety and durability testing, and Muehrcke would expect that, once Braun had an improved filter, it would

stop selling the less safe filter, would inform physicians of the concern of migration, and would get FDA clearance to sell the improved filter. (ECF No. 63-3 at 23-24, opinion 23.)

3.2.2. Analysis

Rivers contends that "Muehrcke is not being proffered as a regulatory expert or expert as to device manufacturer standards" (ECF No. 89-2 at 7) but is instead offering "a practitioner's perspective" (ECF No. 89-2 at 8).

As a cardiothoracic surgeon with extensive experience in treating patients with the filters at issue here, many of Muehrcke's opinions fall within the scope of his expertise and are otherwise admissible under Rule 702. Muehrcke can interpret Rivers's medical records and opine that certain symptoms, treatments, and complications were likely the result of the migration of the filter. (ECF No. 63-3 at 15-16, opinions 2 (in part) 3, 4, 5, 7, and 8.) He can also offer the opinion that Rivers will likely need a second valve replacement in her lifetime. (ECF No. 63-3 at 16, opinion 6.) The fact that he apparently did not consider Rivers's various unrelated health problems in determining whether she was likely to live long enough to need a second valve replacement is a matter for cross-examination.

As an experienced practitioner, he can also offer an opinion as to the information that a reasonable practitioner would expect to receive from a medical device manufacturer, but he must be careful not to stray into matters regarding the legal or regulatory sufficiency of any warning. (ECF No. 63-3 at 23-24, opinions 23 and 24);

Bailey v. B. Braun Med., Inc., No. 1:16-CV-1544-LMM, 2021 U.S. Dist. LEXIS 210853, at *11-*12 (N.D. Ga. Sep. 3, 2021). His lack of familiarity with the legal strictures of medical device warnings is otherwise a matter for cross-examination.

Muehrcke also opines, "It is very unlikely the laparoscopic bypass surgery caused her Braun IVC filter to migrate." (ECF No. 63-3 at 15, opinion 1.) While Muehrcke is an experienced cardiothoracic surgeon, he does not state that he has ever performed a laparoscopic bypass surgery. Although he broadly opines that no aspect of the surgery caused the filter to migrate, he considered only one aspect of the laparoscopic bypass surgery—the gas used to inflate Rivers's abdomen during the procedure. He notes that the gas exerts a pressure lower than that exerted in routine physical activities. (ECF No. 63-3 at 15, opinion 1.) And, in any event, because the pressure is in the abdomen, it would tend to compress the vein and hold the filter in place rather than dislodge it. (ECF No. 63-3 at 15, opinion 1.)

That narrow opinion—that the gas used in the laparoscopic bypass surgery was unlikely the cause the migration—is adequately supported. However, Muehrcke has not offered any other basis for his broader opinion—that it is unlikely that any other aspect of the laparoscopic bypass surgery caused the migration. There is no evidence that he has expertise in laparoscopic bypass surgery, and he did not say in his report that he considered whether any other aspect of the procedure could have caused or contributed to the migration.

Muehrcke may be competent to opine whether open-heart surgery would have been necessary had the migration been identified earlier. But he does not offer such an opinion. Instead, when he says that open-heart surgery would have been necessary even if the migration had been detected immediately after it occurred, he relies entirely on the opinion of Dr. Tanvir Bajwa that percutaneous removal was too dangerous. (ECF No. 63-3 at 17, opinion 9.) While one expert may rely on the opinion of another expert, *Gopalratnam*, 877 F.3d at 789, he may not simply parrot that opinion, *United States v. Brownlee*, 744 F.3d 479, 482 (7th Cir. 2014). According to his report, Muehrcke's sole reason for saying that open-heart surgery was necessary to remove the filter is that Bajwa said it was necessary. That sort of hearsay is not within the scope of Rule 703. *See Richman v. Sheahan*, 415 F. Supp. 2d 929, 941 (N.D. Ill. 2006) (quoting *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002); citing *Loeffel Steel Products v. Delta Brands*, 387 F.Supp.2d 794, 809, 824 (N.D. Ill. 2005)). Muehrcke does not offer a new opinion that relies on Bajwa's opinion for foundation; he simply repeats Bajwa's opinion. Such evidence can come in, if at all, only from Bajwa.

Similarly, Muehrcke relies on the opinions of Dr. Lucas Timmins, who found that the filter Rivers received was defective in its design and testing. (ECF No. 63-3 at 18-20, opinion 13-14.) After recounting Timmins's findings, Muehrcke states, "I find this methodology and conclusion to be reliable and incorporate them into my opinions in this case." (ECF No. 63-3 at 20, opinion 14). But Muehrcke has no training or experience

in the design or testing of medical devices. His opinion amounts to nothing more than an opinion that Timmins's opinions are persuasive. The persuasiveness of an opinion is a matter for the factfinder alone and not an appropriate matter for expert opinion. Muehrcke is not competent to testify as to matters of engineering or metallurgy. *Bailey*, 2021 U.S. Dist. LEXIS 210853, at *8; *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 U.S. Dist. LEXIS 9683, at *300 (D. Ariz. Jan. 22, 2018). And, likewise, he cannot offer an opinion as to whether a product was "defective." (ECF No. 63-3 at 19, opinion 13.)

Nonetheless, insofar as Muehrcke's own opinions rely on the *presumption* that the design or testing of the filter was deficient, he may rely on Timmins's opinions. It will be for the jury to decide whether to accept Timmins's opinions. If it rejects Timmins's opinions, it then will likely reject any dependent opinion of Muehrcke.

Muehrcke also relies on the statistical analysis by Rebecca Betensky regarding the migration rate of the filter Rivers received versus the migration rate of the filter that Braun sold outside the United States. (ECF No. 63-3 at 20, opinion 16.) This is an appropriate use of one expert building on the expertise of another. Muehrcke cannot vouch for Betensky's methods or endorse her conclusion, but he can accept her conclusion insofar as it is a necessary component of an opinion within his expertise. This is little different than an expert relying on any other proffered fact; the proponent must still persuade the jury to find it to be true.

One proffered fact that Muehrcke repeatedly relies on is that the filter sold outside the United States exerted greater radial force than the filter that Rivers received. In simplified terms, radial force is the force of the filter pushing against the walls of the vein, which helps hold the filter in place. Muehrcke points to emails between Braun employees discussing radial force (ECF No. 63-3 at 17, opinion 10), as well as Braun's test results (ECF No. 63-3 at 18-19, opinion 13). Relying on the premise that the filter sold outside the United States had greater radial force than the filter Rivers received, as well as Betensky's data regarding migration rates, Muehrcke offers two opinions: "More likely than not, the 60% increased radial force in the fully deployed Braun VenaTech LP filter sold outside the United States accounted for the significant reduction in the migration rates of these filters"; and, "Had Ms. Rivers had an 'improved LP' OUS Braun IVC filter implanted, instead of the defective US filter, more likely than not her IVC filter would not have migrated, and she would not have suffered her Braun VenaTech IVC filter related travails." (ECF No. 63-3 at 19, opinion 13; *see also id*. at 15, opinion 2.)

While Muehrcke is an expert in implanting and removing filters, he has no known expertise in the mechanics of those filters or in identifying the cause of migration. *Cf*. *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 705 (7th Cir. 2015) ("[A]lthough a doctor may have 'experience diagnosing and treating asthma … that does not make him qualified to assess its genesis.'" (quoting *Cunningham v. Masterwear, Inc.*, 2007 U.S. Dist. LEXIS 29156, 2007 WL 1164832, at *10 (S.D. Ind. Apr. 19, 2007) (Tinder, J.).)

In the Bard MDL, Muehrcke sought to offer testimony regarding the cause of a multi-faceted filter failure. *In re Bard IVC Filters Prods. Liab. Litig.*, 2018 U.S. Dist. LEXIS 9683, at *301. There, the filter broke apart, punctured the vein and surrounding organs, and migrated to the heart. Muehrcke opined that this occurred because the filter had an insufficient ability to resist migration. He did not explain *why* the filter had an insufficient ability to resist migration, merely stating that it did, and that this caused the problems that injured the plaintiff.

But here Muehrcke seeks to go one step further, opining *why* the filter had an insufficient ability to resist migration: because of its lesser radial force than the filter sold outside the United States. However, Rivers has failed to demonstrate that Muehrcke possesses the expertise to opine why the filter had an insufficient ability to resist migration or that he applied a reliable methodology to offer that opinion.

Even if Muehrcke were qualified to testify that radial force affects the migration rate (ECF No. 63-3 at 18, opinion 13 ("The increased radial force the filter exerted on the caval wall reduces the likelihood of migration in a properly deployed filter.")), he has offered no basis for his opinion that the difference in radial force was more likely than not the reason for the difference in migration rates between the two filters. He has identified only a correlation, not causation.

Muehrcke purports to have determined the cause of the filter's migration by employing the methodology of differential diagnosis. (ECF No. 63-3 at 2.) "Physicians

normally use the term [differential diagnosis] to describe the process of determining which of several diseases is causing a patient's symptoms." David P. Leonard, et al., *The New Wigmore: A Treatise on Evidence* §3.5 (2023 Supp. 2010-2020) (citing John B. Wong et al., "Reference Guide on Medical Testimony," *Reference Manual on Scientific Evidence: Third Edition* 687, 690–691 (2011); Bernard D. Goldstein & Mary Sue Henifin, "Reference Guide on Toxicology," *Reference Manual on Scientific Evidence* 401, 416 (Fed. Jud. Ctr. ed., 2d ed. 2000). In legal contexts, however, differential diagnosis is often also used to refer to a method of identifying a cause of a patient's condition. *Id.* To avoid confusion between these distinct concepts, some courts have adopted the term differential etiology to refer to a method of determining causation and limiting differential diagnosis strictly to a method of diagnosing an ailment. *See Higgins*, 794 F.3d at 705 (quoting *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010)). Courts, however, must be mindful that "differential etiology is a legal invention not used by physicians." John B. Wong et al., "Reference Guide on Medical Testimony," *Reference Manual on Scientific Evidence: Third Edition*, 691 (2011).

Using differential etiology for determining the cause of an impairment is a widely accepted methodology, *Robinson v. Davol Inc.*, 913 F.3d 690, 696 (7th Cir. 2019), pursuant to which an expert reaches a conclusion regarding the likely cause of an impairment by, in effect, applying Sherlock Holmes's method of deduction: "[W]hen you have eliminated all which is impossible, then whatever remains, however

improbable, must be the truth." Arthur Conan Doyle, *The Sign of Four*, ch. 6 (1890). Whether an expert reliably applied a differential etiology must be determined on a case-by-case basis, with focus on which potential causes the expert ruled in and which he ruled out. *Myers*, 629 F.3d at 644 (citing *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007). "[A]n expert's decision to 'rule in' or 'rule out' potential causes must itself be 'scientifically valid.'" *Robinson*, 913 F.3d at 696 (quoting *Ervin*, 492 F.3d at 904). But an "expert need not exclude all alternatives with certainty." *Brown v. Burlington N. Santa Fe Ry.*, 765 F.3d 765, 773 (7th Cir. 2014) (citing *Gayton v. McCoy*, 593 F.3d 610, 619 (7th Cir. 2010)).

Differential etiology satisfies *Daubert* provided the expert made "scientifically valid decisions as to which potential causes should be 'ruled in' and 'ruled out,'" *Ervin*, 492 F.3d at 904 (citing *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005)); *see also Higgins*, 794 F.3d at 705 ("But, to be validly conducted, an expert must systematically 'rule in' and 'rule out' potential causes in arriving at her ultimate conclusion."); *Myers*, 629 F.3d at 644 ("Differential diagnosis is an accepted and valid methodology for an expert to render an opinion about the identity of a specific ailment."); *Brown*, 765 F.3d at 773 ("there is 'nothing controversial' about using differential etiology to establish legal cause" (quoting *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 433 (7th Cir. 2013)).

It appears from his report that Muehrcke considered only two explanations for the migration—the gas used in the laparoscopic bypass surgery and the lower radial force of the filter as compared to the Braun filter sold outside the United States. Braun, while noting that a differential etiology is not reliable if a physician "ignores a significant potential cause" (ECF No. 63-1 at 20 (quoting *Sherer-Smith v. C.R. Bard, Inc.*, 2020 WL 1470962, at *4 (W.D. Wis. Mar. 26, 2020)), does not specify any significant potential cause that Muehrcke failed to consider. Instead, it argues that Muehrcke failed to consider how Rivers's obesity may have contributed to the migration of the filter. (ECF No. 63-1 at 21.)

Rivers's obesity is not a cause distinct from the filter's lack of migration resistance. Implicit in Muehrcke's opinion is the conclusion that Braun's filter should have been able to resist migration notwithstanding Rivers's obesity and ordinary life activities. After all, there is no evidence that Braun warned against the use of the filter in obese patients. When a properly implanted filter migrates, it must be because either it has insufficient migration resistance or there was an extraordinary force. The only extraordinary force that Muehrcke considered (and ruled out) was insufflation during laparoscopic surgery.

Braun having failed to identify any significant potential cause that Muehrcke failed to consider, the court cannot conclude that his differential etiology was unreliable. In any event, an expert's failure to consider a particular alternative

explanation is ordinarily a matter for cross-examination. *See Myers*, 629 F.3d at 645 (citing *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 586-87 (7th Cir. 2000)).

As for Muehrcke's opinion that migration would not have occurred if Rivers had received the other filter, that is purely a matter of statistical probability without regard for variables. Muehrcke seems to have treated the risk of migration as if it were a random event, equally distributed across the population of patients. Thus, he concluded that, if Rivers had received a device with a significantly lower migration rate, statistically it is more likely than not that Rivers's filter would not have migrated. However, he has not pointed to any reliable principle, method, or authority to suggest that the likelihood of complications from medical devices generally, much less migration of venous filters specifically, may be assessed in this simplistic manner.

While the filter sold only outside the US might have been less likely to migrate generally, whether Rivers would not have experienced migration with that filter depends on why some of those filters also migrated. For example, as noted above, there is evidence that obesity significantly affects the migration rate. (*See, e.g.*, ECF No. 63-3 at 21, opinion 18.) Were the different migration rates attributable, at least in part, to a difference in the obesity rates in the populations of patients who received the respective filters? If so, then, notwithstanding the increased radial force of the filter sold outside the United States, as an extremely obese person Rivers's personal risk of migration with that filter may have been significantly higher than the overall population of patients

that received the filter sold outside the United States and it might not be possible to say that migration likely would have been avoided with that filter had it been used.

Muehrcke's failure to consider anything beyond the statistical variation in the migration rates between the two filters fundamentally undermines his methodology. Having failed to point to any reliable principle or methodology demonstrating that Rivers's migration risk with the other filter would have decreased at a corresponding rate, Muehrcke cannot opine that it is more likely than not that the filter would not have migrated if Rivers had received Braun's filter sold outside the United States.

Muehrcke's lack of expertise in the design, testing, sale, or regulation of medical devices also undermines his ability to offer certain other opinions. He does not point to any reliable methodology for his opinion: "Why Braun continued to sell a filter with design flaws (Timmins report) in the US is problematic." (ECF No. 63-3 at 20, opinion 16.) Because he does not profess to have any expertise in how a medical manufacturer reports adverse events to the FDA, he cannot offer the opinion, "Braun incorrectly reported the Rivers adverse event to the FDA." (ECF No. 63-3 at 22, opinion 20.) Unlike in *Bailey v. B. Braun Medical, Inc.*, 2021 U.S. Dist. LEXIS 210853, where the court allowed Muehrcke to testify that Braun made the report to the FDA only after the lawsuit was filed, *id*. at *12, here Muehrcke seeks to testify as to the veracity (and, in effect, legal sufficiency) of Braun's report. Such a question is not within his expertise.

Nor does Muehrcke have any expertise in the adequacy of human trials necessary for FDA approval of a medical device and therefore cannot offer the opinion, "Braun likewise performed inadequate human clinical studies with their filter to obtain FDA clearance." (ECF No. 63-3 at 23, opinion 22.) Again, he has no experience in the testing of medical devices and so cannot testify as to the adequacy of the "bench testing" performed by Braun. (ECF No. 63-3 at 19, opinion 13.)

The basis for Muehrcke's opinion that it was "very misleading" for Braun to state that its filter was cleared by the FDA for safety and effectiveness is unclear. (ECF No. 63-3 at 23, opinion 21.) Again, he is not an expert in the regulation of medical devices. It is unclear if he is simply unfamiliar with the FDA "clearance" process, also known as a 501(k) clearance. U.S. Food and Drug Administration, 510(k) Clearances, https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances. That would seem unlikely for a physician experienced with medical devices. Is he simply noting that a 501(k) clearance need not include the same sort of randomized trials as a new medical device? If so, then it is unclear how Braun's statement was misleading. Muehrcke does not suggest that a reasonable physician would have found the statement misleading. And given the ubiquity of the 501(k) process, it is unclear on what basis Muehrcke would be able to offer such an opinion. Without grounding this statement in some sort of reliable principle or methodology, it is not a proper expert opinion.

Without expertise in the regulation and sale of medical devices, Muehrcke lacks a sufficient basis to offer the opinion about his expectations as to what Braun would have done under the circumstances presented. (ECF No. 63-3 at 23-24, opinion 23.) Moreover, his subjective expectations are immaterial to any issue in this case. He does not profess to offer an objective opinion as to what either a reasonable physician would have expected or what a reasonable medical device manufacturer would have done. Therefore, he may not offer the opinion, "I would expect them the [sic] 1) stop selling the defective filter (Timmins' report), 2) inform implanting physicians about the safety concern related to the increased migration rates of their IVC filter, and 3) get FDA clearance for the improved OUS IVC filter." (ECF No. 63-3 at 23-24, opinion 23.) However, Muehrcke may offer an opinion as to the actions of a reasonable physician within his field of expertise.

As for Muehrcke's opinion that Braun underestimated the migration rate of its filters (ECF No. 63-3 at 21-22, opinion 19), he points to research studies that have found that physicians under-report problems with medical devices. He also states that, when a migration occurred because the filter was improperly implanted, Braun did not count that as a migration. He opines that this was improper. And when calculating the migration rate, Braun compared the number of migrations against the number of units sold. But because a hospital may have filters in stock that have not yet been used, the denominator of the ratio was inflated; any filters that were never implanted were

obviously at no risk of migrating. To determine how often filters migrated Braun would need to compare the number of migrations with the number of filters implanted, not sold.

In *Bailey v. B. Braun Medical, Inc.*, 2021 U.S. Dist. LEXIS 210853, the court denied the defendant's motion to exclude in toto Muehrcke's testimony on this subject. *Id.* at *14. But the court limited his testimony to how he, as a physician, considers data regarding problems with medical devices and how he relies on studies such as those he discussed in his report. *Id.* at *14-15.

Muehrcke can testify as to his experience as a practitioner regarding hospitals keeping extra filters on hand and how practitioners interpret adverse event reporting to the FDA in light of evidence of under-reporting. But he cannot testify as to the accuracy or propriety of Braun's actions.

Muehrcke also offers certain opinions that are perhaps best characterized as simply inappropriate asides. For example, at times he opines as to Braun's subjective knowledge or intent or the veracity of certain statements. (*See, e.g.*, ECF No. ECF No. 63-3 at 17, opinion 10 ("This is not factually accurate."); *id*. at 18, opinion 11 (stating that Braun "was so concerned" and had "hopes of increasing migration resistance"); *id*., opinion 12 (stating that Braun "was fully aware"); *id*. at 21, opinion 17 ("Braun's internal documents reveal that they were aware the 'improved LP' filter sold OUS was better than the US filter being sold."); *id.* at 24, opinion 24 ("Braun continued to market the

device, knowing full well they had a better IVC filter being sold outside the United States"). His assertion, "The goal should be patient safety, not corporate profit" (ECF No. 63-3 at 24, opinion 23), is irrelevant and argumentative. Such statements are not proper expert opinions and must be excluded. *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1326 (M.D. Fla. 2015); *Baldonado v. Wyeth*, No. 04 C 4312, 2012 U.S. Dist. LEXIS 68691, at *25-27 (N.D. Ill. May 17, 2012).

3.2.3. Conclusion as to Muehrcke

Braun's motion to exclude Muehrcke will be granted in part. He cannot offer an opinion about Braun's subjective state of mind, adverse event reporting, adequacy of its human trials, the 501(k) clearance process, or his expectations as to what Braun would have done under the circumstances. Nor can he offer the various tangential comments that he peppers his report with. Although Muehrcke can offer his opinion that the gas used in Rivers's surgery was unlikely to cause the filter to migrate, he cannot offer an opinion that no other aspect of the surgery could have caused the filter to migrate. Nor can Muehrcke testify that Rivers would have needed open-heart surgery even if the migration had been detected immediately. The only basis for that opinion is Bajwa's opinion to that effect. Similarly, he cannot testify that he finds Timmins's opinions reliable or repeat them as his own. Finally, Muehrcke's opinion that the filter would not have migrated if Rivers received the version sold outside the United States is not the

product of any reliable methodology because Muehrcke considered the matter only on a macro statistical level and without any consideration of any factor specific to Rivers.

In all other respects Rivers has demonstrated that Muehrcke's opinions are within his expertise and the product of a reliable methodology.

3.3. Lucas H. Timmins

Lucas H. Timmins is an assistant professor of biomedical engineering with 15 years of experience and expertise in the mechanics of cardiovascular soft tissues. (ECF No. 62-3 at 29.) He reviewed the filter at issue and subjected it and the similar filter that Braun sold outside the United States to computer modeling. He also reviewed Braun testing data.

3.3.1. Timmins's Opinions

Timmins concluded that the filter that Rivers received was unsafe and that there was a safer design.

The filter is comprised of eight wires, each bent into roughly triangular forms that come together at a center point to form a conical structure. At the base of each stabilizing leg the wire is coiled into a small loop, similar to the spring mechanism found in a safety pin. This coil causes the filter to expand outward, thus applying radial force to the vascular wall. This coiled loop design, in Timmins's opinion, was more likely to collect platelets and blood clots than a crossing loop design, which could then

cause the filter to migrate. (ECF No. 62-3 at 7.) It also exerted less radial force than the alternative crossing loop design. (ECF No. 62-3 at 27.)

The filter also had barbs on the outermost part of each wire. The barbs were designed to poke into the wall of the vein and help hold the filter in place. These barbs protruded at a very acute angle (only two degrees), which in Timmins's opinion meant that the barbs would minimally penetrate the innermost layer of the vein. If the angle was greater or the barbs longer, they could penetrate deeper into the wall of the vein and better hold the filter in place. Moreover, the barbs were not all placed in the same relative positions around the filter; if viewed along the vertical axis, there were four barbs that were high on the filter and four that were low on the filter. In Timmins's opinion, this meant that it was less likely that all eight barbs would engage into the wall of the vein.

3.3.2. Analysis

For starters, Braun asks the court to exclude numerous opinions that Rivers asserts Timmins has no intention of offering. (ECF Nos. 62-1 at 9-10; 81-2 at 10-11.) Rivers states that Timmins will not offer any opinion on medical causation or any opinion not presented in his report. (ECF No. 81-2 at 10.) Therefore, the court addresses here only the opinions presented in his report and disregards any opinion arising solely from his deposition.

3.3.2.1. State of Mind

Timmins improperly opined as to Braun's subjective state of mind when he stated, "It is of my expert opinion that the tests conducted by B. Braun Medical, and others demonstrate a concern for migration of the VenaTech® LP IVC. The filter design modifications integrated into the new version highlight that design defects were present in the current version." (ECF No. 62-3 at 12.) That is not merely an opinion as to the engineering purpose of a test, *cf. Bailey v. B. Braun Med., Inc.*, No. 1:16-CV-1544-LMM, 2021 U.S. Dist. LEXIS 210852, at *21 (N.D. Ga. Sep. 3, 2021), but an improper opinion about the company's subjective motivations, *see Ind. GRQ, LLC v. Am. Guarantee & Liab. Ins. Co.*, No. 3:21-cv-227 DRL, 2023 U.S. Dist. LEXIS 83671, at *11 (N.D. Ind. May 12, 2023) ("an expert can no better assess subjective intent (improper motive or ill will) than the jury"); *Baldonado*, 2012 U.S. Dist. LEXIS 68691, at *26 (discussing cases). The jury can decide whether the evidence supports the inference that Timmins makes. And while Timmins may be able to refer to, identify, or discuss "what information and knowledge was available to the manufacturer" (ECF No. 81-2 at 12), the subjective motives of the defendant are not subjects within his expertise and thus are not matters on which he may opine.

However, an observation about the nature of Braun's testing—*e.g.*, that Braun performed tests that assessed the migration resistance of a device—does not constitute an improper opinion as to a company's state of mind or subjective motivations. *Bailey*,

2021 U.S. Dist. LEXIS 210852, at *21. Only if the expert intrudes on the province of the jury and suggests the inference that must be drawn from the fact of the testing—that Braun was subjectively concerned about migration—is the opinion improper. In other words, as an engineer, Timmins can opine as to why an engineer would conduct a test—*e.g.*, that an engineer would use the test to assess the filter's vulnerability to migration. But Timmins lacks the experience or expertise to opine as to why a company would order a test, *e.g.*, that the company performed the test because it was concerned that its device was susceptible to migration.

3.3.2.2. Qualifications

Braun does not challenge Timmins's qualifications to offer his opinions other than to note that he has no prior experience with this type of filter. That lack of specific experience does not mean he is unqualified to offer the opinions he presents. Experts qualified to offer opinions on the broader subject matter routinely offer opinions without directly equivalent experience. *See Baugh v. Cuprum S.A. De C.V.*, 845 F.3d 838, 846 (7th Cir. 2017) (finding engineer qualified to testify regarding design of ladder without having ever before designed a ladder or worked in the ladder industry); *Superior Aluminum Alloys, LLC v. United States Fire Ins. Co.*, No. 1:05-CV-207, 2007 U.S. Dist. LEXIS 46688, at *16 (N.D. Ind. June 25, 2007). Timmins is well-qualified in the field of cardiovascular medical devices, including stents, which, like filters, "require[] consideration of the risks of migration, fatigue, and perforation." *In re: Cook Med., Ivc*

Filters Mktg., Sales Practices & Prod. Liab. Litig. This Document Relates To: Elizabeth Jane Hill, 1:14-Cv-6016-Rly-Tab, No. 1:14-ml-02570-RLY-TAB, 2017 U.S. Dist. LEXIS 229989, at *4 (S.D. Ind. Oct. 19, 2017) (finding expert experienced with stents qualified to offer an opinion regarding filters).

3.3.2.3. Coiled Loop Design

As to his substantive opinions, Braun argues that Timmins lacks a sufficient basis for his opinions that the coiled loop design was unsafe and the barbs were insufficient to hold the filter in place. (ECF No. 62-1 at 13-15.) For his opinion regarding the coiled loop design, Timmins generally relied on scientific articles addressing arterial stents rather than venous filters. (ECF No. 62-1 at 14.) He did not rely on any authority for his opinion that the barbs should engage with the second layer of the vein wall. (ECF No. 62-1 at 14.) And there is no evidence suggesting that the barbs did not lie on the same circumferential plane when implanted. (ECF No. 62-1 at 14.)

Timmins did not blindly apply conclusions regarding arterial stents to venous filters. (ECF No. 62-3 at 6-7.) He explained how the environments were analogous in material respects and how the circumstances that made the coiled loop design unsafe reflect well-established principles of fluid dynamics. (ECF No. 62-3 at 6-7.) An expert's opinion need not always be supported by directly on-point research. Often the work of an expert is to take analogous research and apply it to the novel facts of the case. Provided there was a reliable basis for the analogy, the fact that Timmins relied on

research regarding arterial stents to assess the performance of venous filters is not a reason to exclude his opinions.

Timmins's report adequately demonstrates that his opinions regarding the safety of the coiled loop design were the product of a reliable methodology. His opinion relied on tested and published principles, albeit those arising largely in the context of arterial stents. He has explained how the arterial and venous environments are sufficiently analogous to merit comparison and how the principles that underlie his opinion are "broadly observed in both fluid dynamics and aerodynamics across the engineering disciplines." (ECF No. 62-3 at 7.)

Braun argues Timmins could have done more to test his opinion. (ECF No. 97 at 7-8.) But an opinion is not inadmissible merely because an expert could have done more. Admissibility depends on whether an expert did enough. Timmins did; the fact that he did not do more is a matter for cross-examination. Therefore, Braun's motion to exclude Timmins's opinion regarding the coiled loop design will be denied. *See Bailey*, 2021 U.S. Dist. LEXIS 210852, at *8 (denying motion to exclude similar opinion of Timmins).

3.3.2.4. Barbs

As for Timmins's opinions regarding the barbs on the filter, he states, "While the barbs are designed to prevent caval wall perforation, the barbs must engage the tissue, which at a minimum requires perforation of the *tunica intima* and engagement of the

tunica media." (ECF No. 62-3 at 8.) In other words, it is Timmins's opinion that the barbs need to go through the innermost layer of the vein and stick in the second layer without poking through the third layer, perforating the vein.

Timmins does not cite any authority for that opinion, and Rivers makes no effort to defend it in response. It will be excluded.

However, Timmins's opinions regarding the barbs were not limited to the depth at which the barbs must penetrate. He also offered calculations on the depth at which the barbs would penetrate given their angle and length. Notwithstanding the exclusion of his opinion as to how far the barbs *should* penetrate, evidence as to how far they *did* penetrate remains relevant. A layperson can recognize that prongs that penetrate deeper are likely to do a better job holding an object in place. Timmins's opinion is also the product of a reliable methodology that he is qualified to apply—basic centuries-old trigonometry—and therefore admissible.

Braun also argues that the court must exclude Timmins's opinion that the barbs would not lie on the same circumferential plane when implanted. (ECF No. 62-1 at 14.) While it is the proponent's burden to show that an expert's opinion is the product of a reliable methodology, not every shot-in-the-dark criticism, what-if, or variation between tests and the facts of the case is a basis for excluding an opinion. Timmins testified that it was "blatantly obvious" from the design schematics that the barbs are not on the

same plane. And it appears undisputed that, of the eight barbs, four are lower than the other four. (*See* ECF No. 62-3 at 5, Fig. 1.)

Nonetheless, Braun seems to suggest that something might happen to the shape of the filter when it is implanted so that the relative position of the barbs could shift. It offers no support for this notion; it notes merely that Timmins did not evaluate the positioning of the barbs when the filter was implanted in a vein. Without reason to believe that it is plausible or material, this sort of hypothetical what-if does not undermine the reliability of an expert's opinion. Timmins reliably opined that the position of the barbs would decrease the likelihood of all eight barbs embedding in the wall of the vein. Whether all eight barbs actually would be likely to engage the vein wall, whether engagement of all eight barbs was necessary to resist migration, and the fact that Timmins did not test his opinion by evaluating the filter when implanted in a vein are all matters for cross-examination.

Rivers has demonstrated that Timmins is both qualified to offer and applied a reliable methodology to arrive at his opinion that, "Collectively, these design features [—the coil loop design, the size of the barbs, and the position of the barbs—] limit the stability and securement of the filter and increase the likelihood of device migration." (ECF No. 62-3 at 9.)

3.3.2.5. Safer Alternative Design

Timmins opines that a reasonable alternative design is embodied in the filter that Braun sold outside the United States. To support this opinion, Timmins relied on Braun's own testing data (ECF No. 62-3 at 10-12), finite element analysis, which involved computer modeling (ECF No. 62-3 at 12-25), and a comparison between the reported migration rates of the two filters (ECF No. 62-3 at 25-26).

Braun faults Timmins for simultaneously criticizing the sufficiency of Braun's testing and relying on that testing to support his opinion that the filter sold outside the United States was safer.

Notwithstanding Timmins's criticism that Braun's testing did not reflect real world conditions, it allowed for an apples-to-apples comparison between the two filters. In other words, even if the performance of the filters in the real world would be different from how they performed in the testing environment, those variations would be the same between both filters. There is no evidence that the design variations between the two filters would have resulted in a negative correlation in the performance of the filters when implanted or tested under conditions more reflective of real-world conditions. Thus, it is not necessarily inconsistent or problematic for Timmins to criticize Braun's testing as insufficient to measure real-world performance of its filters and to then rely on that testing to conclude that the filter Braun sold outside the United States embodied a safer alternative design.

As for Timmins's computer modeling, "'[a] mathematical or computer model is a perfectly acceptable form of test' for a proposed alternative design." *Baugh*, 845 F.3d at 845 (quoting *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 815 (7th Cir. 2012); citing *Cummins v. Lyle Indus.*, 93 F.3d 362, 369 (7th Cir. 1996)). Nonetheless, Braun faults Timmins's computer modeling because he "failed to perform proper validation experiments and used input data that does not accurately represent the behavior of the VenaTech LP when implanted in the human body." (ECF -No. 62-1 at 8.)

In his report Timmins states, "Unlike many commercial finite element packages, the open-source FEBio platform has undergone extensive verification and validation to demonstrate solution accuracy." (ECF No. 62-3 at 13-14.) But this assertion is not explained. Aside from some unrelated discussion in her response to Braun's motion to exclude Betensky's opinion (ECF No. 87-2 at 14-15), Rivers's response made scant effort to defend Timmins's computer modeling and does not explain how it was reliable despite Timmins failure to validate it. Without proof that the finite element analysis accurately modeled the performance of the two filters, Timmins cannot rely on that modeling to support his opinion that filter sold outside the United States was a safer alternative design.

Braun further argues that Timmins improperly parrots the opinions of Rebecca Betensky regarding the statistical variation between the two filters. (ECF No. 62-1 at 22-23.) As discussed above with respect to Muehrcke's opinions, reliance on another

expert's opinion is different than parroting an expert. Improper parroting occurs when an expert repeats as his own the conclusion of another expert, *see Ashley Furniture Indus., LLC v. Perficient, Inc.*, No. 21-cv-622-jdp, 2023 U.S. Dist. LEXIS 119335, at *27 (W.D. Wis. July 11, 2023), or acts as "the mouthpiece of a scientist in a different specialty," *Dura Auto. Sys.*, 285 F.3d at 614. Frequently, this will be accompanied by some sort of expression that he finds the other expert's conclusion persuasive or his method reliable. Reliance on another expert's opinion, however, is proper and occurs when an expert uses another expert's opinion to support a distinct opinion. *See In re James Wilson Assocs.*, 965 F.2d 160, 173 (7th Cir. 1992).

Timmins notes that Betensky's statistical analysis showed that the filter Braun sold outside the United States migrated less than the filter Rivers received. Timmins relied on that opinion to support his opinion that the other filter represented a safer alternative design. (ECF No. 62-3 at 26 ("These statistical data augment the experimental and computational data reported in this report that the OUS device provided increased radial force than the US device and thus greater resistance to cephalad migration.").)

It was appropriate for Timmins to rely on Betensky's opinion. If the jury rejects Betensky's opinion, it may reject Timmins's opinion that relies on it. But Timmins's reliance on Betensky's opinion does not make Timmins's opinion improper.

As for Timmins's ultimate opinion that the filter Braun sold outside the United States represented a safter alternative design, Rivers has shown that this opinion was the product of a reliable methodology. As discussed above, Timmins applied a reliable methodology to arrive at the opinion that the coil loop design, as well as the position, size, and angle of the barbs, rendered unsafe the filter the Rivers received and certain changes would make the filter safer. Those changes were embodied in the filter that Braun sold outside the United States, which was shown to migrate less. Even without his computer modeling, Timmins's methodology was reliable.

3.3.3. Conclusion as to Timmins

Braun's motion with respect to Timmins will be granted in part. Aside from opinions not reflected in his report, and which Rivers states she has no intention of presenting at trial, Timmins is barred from offering any opinion as to Braun's state of mind or subjective motivations. Timmins further is unable to offer the opinion that the barbs of the filter must, at a minimum, engage the *tunica media*. Nor may Timmins rely on his finite element analysis to support his opinion that the filter Braun sold outside the United States represented a safer alternative design. As to all other opinions in his report, Rivers has demonstrated that Timmins is qualified to offer the opinions and that each is the product of a reliable methodology. Therefore, Braun's motion will be denied in all other respects.

3.4. Rebecca Betensky

3.4.1. Betensky's Opinions

Betensky has a doctorate in statistics and is a professor of biostatistics. (ECF No. 57-3 at 2.) She reviewed Braun's sales and migration data for both (a) the type of filter that Rivers received and (b) the type of filter that Braun sold only outside the United States. (ECF No. 57-3 at 2.) As to the former, she reviewed data from 2000 through May 2016; as to the latter, because that filter was first sold in 2010, she reviewed data from 2010 through June 2016. (ECF No. 57-3 at 2.) She parsed the migration data into three groups—migration when the filter opened; migration when the filter did not open; and any migration. She applied two different statistical tests to each group of data—the Exact Mantel Haenszel test and Fisher's exact test. (ECF No. 57-3 at 2.) The Exact Mantel Haenszel test adjusted for year and, therefore, because the filter sold outside the United States was first sold in 2010, she did not consider data before 2010 when applying this test. (ECF No. 57-3 at 2.) As to the Fisher's exact test, she performed the test on two sets of data—once using only data from 2010 and after, and then using all available data. (ECF No. 57-3 at 3.)

Although stated in the jargon of statistics, in simple terms Betensky's analysis showed that, when the filter opened, the filter sold outside the United States was reported to have migrated less frequently than the type of filter that Rivers received.

(ECF No. 57-3 at 2-3.) When the filter did not open, there was not a significant difference in the rates at which migration was detected. (ECF No. 57-3 at 3.)

3.4.2. Analysis

Braun argues that Betensky's opinions should be excluded because she made no effort to determine the comparability of the underlying data. For example, the filter sold outside the United States might not actually be less susceptible to migration but instead might be used in patients at lower risk of migration, be used in circumstances less likely to lead to migration, or be less likely to be detected when migration does not lead to symptoms. (ECF No. 57-1 at 10-15.)

Braun's criticism rests on a misstatement of Betensky's opinions as set forth in her report. She assessed only the statistical relationship between the data. She did not purport to determine the cause of that statistical relationship. Nor did she purport to apply her opinions to Rivers's alleged injuries. The fact that she did not attempt to determine what might explain the different migration results does not undermine the reliability of her methodology.

Disagreements as to the methodology employed (ECF No. 57-1 at 16-17) do not demonstrate that Betensky's methodology was unreliable but rather are matters for cross-examination. *See Angelopoulos v. Keystone Orthopedic Specialists, S.C.*, No. 12-cv-5836, 2017 U.S. Dist. LEXIS 74102, at *19, 119 A.F.T.R.2d (RIA) 2017-1882 (N.D. Ill. May 16, 2017) (citing *Smith*, 215 F.3d at 718). There is often more than one way to attack a

problem, and Rivers has demonstrated that Betensky's methodology provided a reliable basis for her opinions.

Braun further criticizes Betensky's reliance on data of migrations occurring after Rivers received her filter. It argues that relying on such data renders Betensky's opinion irrelevant and unhelpful.

"[E]xpert testimony must be helpful to the jury to be admissible." *United States v. Parkhurst*, 865 F.3d 509, 516 (7th Cir. 2017) (quoting *United States v. Christian*, 673 F.3d 702, 710 (7th Cir. 2010)). But data need not predate Rivers's surgery for it to be relevant to the question of whether the filter sold outside the United States was a safer alternative. For example, a plaintiff could establish that Product A was a safer design than Product B by conducting an experiment, providing one population with Product A and another population with Product B, and then tallying the injuries. All such data would be acquired after the plaintiff's injury, but nonetheless would be relevant and helpful to the jury in determining whether Product A was safer. Betensky simply relied on real world data instead of a controlled experiment.

Finally, although middle school level mathematics may identify similar relationships in the data, Betensky's actual methodology and opinions cannot be fairly characterized as "little more than basic arithmetic that any lay person on the jury could do for themselves." (ECF No. 57-1 at 17.) Betensky's opinions were the product of

specialized knowledge not obvious to a layperson, *see Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 484 (7th Cir. 2020), and therefore proper matters for an expert.

Braun's motion to exclude Betensky as an expert will be denied.

3.5. Jennifer Cook

3.5.1. Cook's Opinions

As discussed below, Leigh Anne Levy is a registered nurse and Certified Life Care Planner. (ECF No. 60-3 at 93.) She prepared a "Life Care Plan and Cost Analysis" for Rivers. To assist her in preparing that report she retained Jennifer Lynn Cook, a cardiologist, to conduct an independent medical examination of Rivers. Although both Cook and Levy signed the Life Care Plan, only Section "IX. Independent Medical Examination" is attributable to Cook. (ECF No. 60-3 at 97-106.) Nonetheless, Cook closed Section IX by stating, "Ms. Rivers' needs were discussed in detail for inclusion in the Life Care Plan. The full scope of my opinions is reflected in that document." There is no indication that any opinion in the Life Care Plan other than those contained in Section IX is attributable to Cook.

In Section IX Cook stated that the average survival rate for a person following a tricuspid valve replacement is 15 years, and Rivers will require annual echocardiograms as a result of the replacement. (ECF No. 60-3 at 105.) Cook also stated that Rivers has "right heart failure" which will require "therapy to manage fluid retention" and hospital admissions to remove excess fluid. (ECF No. 60-3 at 105-06.) This chronic

progressive disease will lead to liver and kidney disfunction, heart catheterization, treatments to control high blood pressure and kidney problems, including dialysis, and ultimately to palliative care. (ECF No. 60-3 at 106.) Further, Rivers may require medication to address atrial arrythmia and "psychological service and medical therapy" regarding "medical related anxiety." (ECF No. 60-3 at 106.) Finally, Cook noted that Rivers reported "chest discomfort and physical limitations" following her surgery. (ECF No. 60-3 at 106.)

3.5.2. Analysis

3.5.2.1. Rivers's Compliance with Rule 26

"Rule 26(a)(2) of the Federal Rules of Civil Procedure requires the proponent of expert testimony to disclose the witness's identity, along with a written report that contains, among other things, a 'complete statement of all opinions the witness will express and the basis and reasons for them.'" *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 825 (7th Cir. 2010). "The sanction for failure to comply with this rule is the 'automatic and mandatory' exclusion from trial of the omitted evidence, 'unless non-disclosure was justified or harmless.'" *Id.* (quoting *Hammel v. Eau Galle Cheese Factory*, 407 F.3d 852, 869 (7th Cir. 2005)).

In her Rule 26(a)(2) disclosures Rivers identified Cook as an expert. (ECF No. 59-2.) Cook's opinions are included in the Life Care Plan that was prepared primarily by Levy. (ECF No. 60-3.) Provided it is clear which expert is responsible for which

opinions, Rule 26(a)(2)(B) does not prohibit joint expert reports. *See Winters v. Smith*, No. 4:11-CV-49-PPS-PRC, 2015 U.S. Dist. LEXIS 196420, at *2 (N.D. Ind. May 12, 2015).

Appended to the Life Care Plan is Cook's curriculum vitae. It does not appear that a list of her prior cases or a statement of her compensation is included in either the Life Care Plan or Rivers's Rule 26(a)(2) disclosure. However, Braun does not complain about those omissions. Instead, it argues that Cook's report did not comply with Rule 26 in that Cook failed to properly set forth in her report the bases for her opinions. This is more a matter of the sufficiency of Cook's methodology, and accordingly addressed below. But before getting to that, first the court must address Cook's qualifications.

3.5.2.2. Cook's Qualifications

Braun argues that Cook is not qualified to offer her opinions because, although she is a cardiologist, she has no experience with venous filters and has never treated a patient who required tricuspid valve replacement following the migration of a venous filter. (ECF No. 59-1 at 16.) Further, she is not a surgeon and has never performed a valve replacement. (ECF No. 59-1 at 17.)

Cook is experienced in treating patients who have had valve replacements. Braun has not shown that the *reason* for the valve replacement materially affects Cook's ability to opine on Rivers's prognosis. Cook's opinions and expertise relate to Rivers's medical care and condition following the valve replacement, and Rivers has demonstrated that Cook is qualified in that regard.

As for Cook's opinion that Rivers may require "psychological service and medical therapy" regarding "medical related anxiety," that is outside the scope of her expertise. Cook is not a psychologist or psychiatrist. Although her medical training and experience may encompass aspects of identifying or treating certain mental health concerns, that does not constitute expertise to predict Rivers's future mental health needs. *See Myers*, 629 F.3d at 644 (quoting *Gayton*, 593 F.3d at 617 ("The question we must ask is not whether an expert witness is qualified in general, but whether his qualifications provide a foundation for [him] to answer a specific question." (brackets in original))). Experience may give rise to expertise, but not all experience translates into expertise; there is a higher threshold than mere experience for expertise.

Rivers has not demonstrated that Cook has the expertise to offer the opinion that "[s]he will require psychological services and medical therapy to ameliorate these symptoms" of medical related anxiety. (ECF No. 60-3 at 106.) "Simply because a doctor has a medical degree does not make him qualified to opine on all medical subjects." *Gayton*, 593 F.3d at 617. Braun's motion will be granted with respect to that opinion.

3.5.2.3. Analysis of Cook's Methodology and Opinions

At no point does Cook suggest that Rivers's impairments and future treatment needs are connected to an alleged defect in Braun's filter. Braun contends that this renders her opinions inadmissible.

While Rivers must ultimately connect her injuries and impairments with the alleged malfunction of the filter, she need not do so through Cook. It is permissible for an expert to offer opinions about a plaintiff's alleged injuries and leave it to the plaintiff to establish causation through other evidence. Cook is not proffered as a causation expert.

As for Cook's methodology, although physicians are perhaps the most common sort of expert, they often pose difficult problems under *Daubert*. It is well-established that an expert must support her opinion with more than a mere *ipse dixit*. *See, e.g.*, *GE v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."). But a court's role under Rule 702 "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). A physician will routinely offer a patient an opinion in the form of a diagnosis or prognosis without articulating how she arrived at that conclusion. If pressed, even if she can say she learned that certain symptoms or test results indicate a particular conclusion, she might not be able to trace that knowledge back to any specific research or even text that supports her conclusion. If a physician offers the same sort of opinion in court, it can come across sounding a lot like mere *ipse dixit*.

But courts have found that the combination of the physician's experience and her review of a patient's medical history may constitute a reliable methodology. *See, e.g.*, *Block v. Ethicon, Inc.*, No. 1:19-cv-04546-SEB-TAB, 2020 U.S. Dist. LEXIS 205148, at *9 (S.D. Ind. Nov. 2, 2020); *In re Yasmin & Yaz (Drospirenone) Mktg.*, No. 3:09-md-02100-DRH-PMF, 2011 U.S. Dist. LEXIS 145588, at *18 (S.D. Ill. Dec. 16, 2011) ("Thus, as Dr. Rinder bases his opinion on a reliable methodology; specifically, his experience and relevant medical knowledge, the Court finds his opinions as to plaintiff's prognosis, including her possible future harm, and damages admissible."); *cf. Kumho Tire*, 526 U.S. at 156 ("no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience").

Cook reviewed Rivers's medical history, performed a physical examination (by videoconference), and applied her medical training and experience to reach conclusions as to Rivers's diagnosis, prognosis, and future treatment needs. This is an ordinary, accepted, and reliable methodology. *See In re Yasmin & Yaz (Drospirenone) Mktg.*, 2011 U.S. Dist. LEXIS 145588, at *18. This methodology was sufficient to sustain Cook's opinions that Rivers will require annual echocardiograms, her diagnosis that Rivers suffers from right heart failure, and her general prognosis regarding that condition.

However, Rivers has failed to demonstrate that Cook's opinion that the average survival period following tricuspid valve replacement is 15 years is the product of any reliable methodology. Cook does not say where the 15-year figure came from, *e.g.*,

whether it is from a published study of a representative sample of patients or simply Cook's impression from her experience treating similar patients. Patients may frequently seek out physicians to offer an opinion about survival time, and physicians may routinely offer such opinions informed by experience and gut intuition. But to satisfy Rule 702 it must be the product of science. Quantifiable questions like average survival times must be answered with more than a physician's impression, hunch, or speculation, even if it is informed by her experience. *Cf. Leibfried v. Caterpillar, Inc.*, No. 20-CV-1874, 2023 U.S. Dist. LEXIS 106006, at *29 (E.D. Wis. June 20, 2023).

Moreover, even if Cook's opinion were the product of a reliable methodology, Rivers has failed to show that this opinion would be relevant or helpful to the jury or that Cook reliably applied her methodology to the facts of the case. There is no indication that Cook made any effort to determine whether Rivers was an "average patient" such that the 15-year timeline would be applicable.

Cook's opinion that Rivers "may again require anti-arrhythmic therapy with amiodarone" (ECF No. 60-3 at 106), standing alone, is not relevant or helpful. As with all damages, although Rivers need not prove damages with certainty, it is her burden to prove her future medical expenses by a preponderance of the evidence. *Walker v. Baker*, 13 Wis. 2d 637, 650, 109 N.W.2d 499, 506 (1961); Wis. JI-Civ. 202, 1758. To say that Rivers "may" require a particular treatment falls short of her burden and is insufficient to sustain her claim. If Cook's opinion is the only evidence Rivers has to support this

aspect of her claim for future medical expenses, the court must exclude it as irrelevant and unhelpful. *See Alswager v. Rocky Mt. Instrumental Labs., Inc.*, No. 09-CV-52-JPS, 2011 U.S. Dist. LEXIS 102910, at *6 n.1 (E.D. Wis. Sep. 9, 2011) ("[B]ecause Wisconsin law is clear that a medical opinion stating that an outcome is possible, rather than probable, does not rise to the level of reasonable medical certainty, Dr. Lantz's opinion would not have been admissible at Mr. Alswager's criminal trial.") However, if this aspect of Rivers's claim is supported by other evidence, Cook's opinion may be relevant and helpful. If other evidence could support the finding that Rivers is more likely than not going to need anti-arrhythmic therapy with amiodarone, Cook's opinion that she may require such therapy is relevant corroborative evidence. Because the full extent of Rivers's evidence is not yet before the court, it cannot find that this aspect of Cook's opinion is irrelevant or unhelpful.

Similarly, to say that Rivers "should also be considered for atrial fibrillation ablation" (ECF No. 60-3 at 106) is insufficient to support a finding that such future treatment is compensable. But whether Cook's opinion is relevant and helpful will depend on whether Rivers will be able to muster evidence sufficient to sustain a verdict in her favor on this aspect of her claim.

3.5.3. Conclusion as to Cook

Rivers adequately complied with Rule 26 in disclosing Cook as an expert. Cook is not unqualified simply because she lacks experience with venous filters. However, Cook

is not qualified to offer opinions regarding Rivers's mental health. Cook's opinion regarding average length of survival is not the product of a reliable methodology. Nor is it relevant or helpful. Rivers has shown that Cook's remaining opinions are the product of a reliable methodology. As a damages expert, Cook was not required to connect Rivers's alleged injuries to the malfunction of the filter. Whether all of Cook's opinions regarding Rivers's future medical treatment needs are relevant will depend on whether Rivers is able to present evidence from which the jury could find that she will more likely than not require such treatment.

3.6. Leigh Anne Levy

Again, Levy is a registered nurse and Certified Life Care Planner. (ECF No. 60-3 at 93.) She describes a life care plan as a document that "details medical and medically related goods and services that are needed for individuals who have sustained a catastrophic injury or disabling disease, or who have a handicapping condition that has life time needs associated with it." (ECF No. 60-3 at 4.) Developing a life care plan requires a consideration of "[a]ll past medical, social, psychological, vocational, educational, and rehabilitation data" and may include consultation with medical experts. (ECF No. 60-3 at 4.) This is a recognized and accepted methodology for developing a life care plan. *See, e.g.*, *Hopey v. Spear*, No. 13-CV-2220, 2016 U.S. Dist. LEXIS 198969, at *6 (C.D. Ill. Apr. 18, 2016) (citing *Hale v. Gannon*, No. 1:11-cv-277-WTL-

DKL, 2012 U.S. Dist. LEXIS 125756, at *8 (S.D. Ind. Sep. 5, 2012)). The ultimate goal of a life care plan is to calculate the costs of future medical care. (ECF No. 60-3 at 4.)

Braun does not challenge Levy's qualifications as an expert other than to note that she is not a medical doctor and therefore is not qualified to diagnose any disease, condition, or impairment. Instead, she must rely on other experts for such determinations.

3.6.1. Levy's Reliance on Ross DeVere

Levy hired Ross DeVere, a psychologist, to evaluate Rivers. (ECF No. 60-3 at 4.) Although Levy's Life Care Plan refers to DeVere as "an active team member" in preparing the plan and identifies his psychological inventories as among the "Other Sources of Information" she considered in preparing the plan, the plan does not attribute any particular opinion to DeVere.

Braun moved to exclude DeVere's opinions in part because Rivers did not disclose him as an expert. (ECF No. 60-1.) However, it likewise does not identify any specific opinion offered by DeVere that it wants to keep out.

Rivers responds that this aspect of Braun's motion is moot because DeVere will not be testifying at trial. (ECF No. 85-1 at 4.) Nonetheless, she contends that Levy may appropriately rely on DeVere's opinions. Rivers's support for her argument is scant. She notes that Rule 703 allows an expert to rely on facts and data of which she has been made aware, even if those facts and data are not themselves admissible, provided they

are of the sort that experts in the field reasonably rely on. And so one expert's opinion may build on the expertise of another expert. (ECF No. 85-1 at 6-7 (quoting *Dura Auto. Sys.*, 285 F.3d at 613).) In Rivers's view, "The germane question for purposes of Rule 702 is whether an expert life care planner would reasonably rely on a recommendation supplied by a clinical psychologist after performing a screening exam, in forming an opinion on a patient's future psychological and psychiatric care needs." (ECF No. 85-1 at 7.)

Rule 703 allows an expert to rely on hearsay in forming her own opinions. It does not authorize an expert to be a conduit for otherwise inadmissible hearsay. *Gong v. Hirsch*, 913 F.2d 1269, 1273 (7th Cir. 1990); § 7:16 Secondhand information—Reasonable reliance standard; limits on disclosure of inadmissible hearsay, 3 Federal Evidence § 7:16 (4th ed.). As with Muehrcke's reliance on Bajwa's conclusions, Levy seeks to offer conclusions supported only by DeVere's say so. It would be one thing if DeVere merely administered tests that Levy was competent to interpret and apply. But Levy lacks such expertise and thus her opinions regarding Rivers's psychological impairments and need for future treatment are DeVere's. Levy cannot be the conduit for opinions of a non-testifying expert.

Moreover, Rule 703 permits a party to disclose underlying opinions like DeVere's to the jury "only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect." The prejudice here is obvious. If

DeVere does not testify (and he cannot because Rivers did not properly disclose him as an expert), Braun has no opportunity to cross-examine him or directly challenge his opinions. DeVere's opinions are not tangential or cumulative but rather the basis for Rivers's claim that she suffered psychological injuries.

The only other authority that Rivers presents, *Walker v. Soo Line Railroad*, 208 F.3d 581, 589 (7th Cir. 2000), is distinguishable. There the court condoned a "leader of a clinical medical team" testifying about the conclusions of the team even though that leader might not have expertise in each member's discipline. *Id.* at 589. The court underscored that such a team is specially employed to work together for the benefit of the patient and the leader is chosen precisely because of her expertise in being able to evaluate each team member's contribution and to craft an overall picture. *Id.*

Levy is not the leader of a clinical medical team but rather a consultant retained to opine on Rivers's future medical needs. She brought in DeVere precisely because she lacked the expertise to offer an opinion on Rivers's psychological state. Although life care planning is a discipline that may routinely "require[] the coordination and management of information from many sources" (ECF No. 60-3 at 4), it is not a means for laundering hearsay statements or evading expert disclosure requirements. Rather than presenting DeVere as an expert, Rivers seeks to have Levy testify as to DeVere's conclusions. One expert cannot be the mouthpiece for another expert in a different specialty. *Dura Auto. Sys.*, 285 F.3d at 614. "An expert who parrots an out-of-court

statement is not giving expert testimony; [s]he is a ventriloquist's dummy." *Brownlee*, 744 F.3d at 482. Braun's motion to exclude DeVere's opinions, either from him directly or through Levy, will be granted.

It is unclear from the parties' briefs or Levy's report which opinions are attributable DeVere. But Levy explained in her deposition that the last four paragraphs of the "Current Complaints" section of the Life Care Plan were drafted by DeVere. (ECF Nos. 60-4 at 26-27, 164:19-165:10; 60-3 at 61-62.) Those facts and the conclusions that Rivers "should be seen for individual psychotherapy, preferably with a licensed psychologist who specializes in treating individuals with PTSD and pain" and she should "continue to follow up with her psychiatrist for pharmacotherapy" (ECF No. 60-3 at 62) are excluded.

3.6.2. Levy's Reliance on Muehrcke and Cook

Levy's opinions regarding Rivers's future medical care rely in part on Muehrcke's and Cook's opinions. Because each is expected to testify, Rivers does not suggest that she intends to admit Muehrcke's and Cook's opinions through Levy. To the extent that Muehrcke's and Cook's opinions are admissible (as discussed above), Levy is entitled to rely on them as a foundation for her opinions. If the jury rejects Muehrcke's and Cook's opinions, it will reject Levy's dependent opinions. Levy, however, may not vouch for or otherwise offer an opinion as to the correctness of any other expert's opinion.

3.6.3. Levy's Opinions as Speculative or Unsupported

Braun argues that Levy's opinions about Rivers's future medical needs are speculative. (ECF No. 60-1 at 17-21.) But such is the nature of any claim for future medical expenses; the future is inherently uncertain. A plaintiff need not prove her damages with mathematical precision but rather only with reasonable certainty. *See, e.g.*, Wis. JI Civil 1700; *Gard v. United States*, No. 20-CV-256, 2022 U.S. Dist. LEXIS 111911, at *30 (E.D. Wis. June 24, 2022). Whether Rivers will be able to sustain her burden will be up to the jury.

The fact that Levy does not connect her opinions to the filter that Rivers received is not a basis to exclude her opinions. Levy is a proffered as a damages expert; Rivers may prove causation through other witnesses.

Nor is it necessary that Levy's opinions neatly coincide with a specific recommendation from one of Rivers's treating physicians. On the one hand, a life care planner's opinions must be grounded in the medical evidence. *See Eliason v. Superior Ref. Co. LLC*, No. 19-cv-829-wmc, 2021 U.S. Dist. LEXIS 198896, at *20 (W.D. Wis. Oct. 15, 2021) On the other hand, one aspect of a life care planner's expertise is to extrapolate from present diagnoses and recommendations to likely future needs. *See Cordes v. Ctrs. for Reprod. Med. & Wellenss, LLC*, No. 3:20-CV-10-MAB, 2023 U.S. Dist. LEXIS 176365, at *31-32 (S.D. Ill. Sep. 29, 2023). It is because physicians' opinions are commonly limited to the past and the present that a life care planner's expertise is necessary. This may

sometimes be a fine distinction to draw. Any perceived lack of support or unjustified leaps in Levy's opinions are matters for cross-examination. Ultimately, it will be for the jury to decide whether to believe Levy's opinions.

However, Braun's criticisms of Levy's identification of future costs for psychological services, "health and behavior psychological services," and a nutritional therapist (ECF No. 60-1 at 22) are well-founded. Cook is not qualified to offer an opinion on Rivers's psychological needs and any opinion of DeVere's was not properly presented. Without those opinions, there is no basis to find that Braun will require future psychological care.

Levy's report is conspicuously devoid of any explanation as to why Rivers would require nearly $7,000 for a nutritional therapist. Levy lists "Nutritional Services" as one of the specialties from which Rivers will require care but next to that listing states only "to assist with." (ECF No. 60-3 at 67.) The thought appears incomplete; no actual explanation is included. Although Rivers asserts that Levy explained her opinion at her deposition, that does not cure the deficiency in her report. *See Ciomber v. Coop. Plus, Inc.*, 527 F.3d 635, 642 (7th Cir. 2008) ("Rule 26(a)(2) does not allow parties to cure deficient expert reports by supplementing them with later deposition testimony.")

Therefore, Braun's motion to exclude Levy from testifying will be granted with respect to her opinions regarding Rivers's need for psychological and nutritional services but denied as to all other grounds.

4. Motions for Summary Judgment

4.1. Summary Judgment Standard

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" only if it "might affect the outcome of the suit" and a dispute is "genuine" only if a reasonable factfinder could return a verdict for the non-movant. *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 248 (1986). In resolving a motion for summary judgment, the court is to "construe all evidence and draw all reasonable inferences from the evidence in" favor of the non-movant. *E.Y. v. United States*, 758 F.3d 861, 863 (7th Cir. 2014) (citing *Gil v. Reed*, 535 F.3d 551, 556 (7th Cir. 2008); *Del Raso v. United States*, 244 F.3d 567, 570 (7th Cir. 2001)). "The controlling question is whether a reasonable trier of fact could find in favor of the non-moving party on the evidence submitted in support of and [in] opposition to the motion for summary judgment." *White v. City of Chicago*, 829 F.3d 837, 841 (7th Cir. 2016).

4.2. Rivers's Motion for Summary Judgment (ECF No. 56)

Rivers asks the court to bar Braun from relying on "the alleged negligence or malpractice of Plaintiff's healthcare providers" as a defense. (ECF No. 56 at 1.) She states, "A number of the Defendants' affirmative defenses rest upon allegations that Plaintiff's implanting physician, bariatric surgeon, cardiologist, and various of her radiologists failed to exercise the degree of skill and learning commonly applied by the

average reputable healthcare provider in their circumstances." (ECF No. 66 at 4.) In her view Braun is attempting to raise a medical malpractice claim, which it lacks standing to assert. (ECF No. 56 at 2-3.)

Braun asserts that various of Rivers's medical providers were negligent by: performing bariatric surgery on her immediately after implanting the filter because the nature of the surgery could cause the filter to move (ECF No. 75 at 17); choosing to use a permanent rather than a retrievable filter, which would have been monitored for movement (ECF No. 75 at 16-17); and failing to recognize on seven imaging studies that the filter had moved to her heart, thus delaying retrieval, allowing the filter to become incorporated into the tricuspid valve of the heart, and increasing complications (ECF No. 75 at 17-18).

The case Rivers primarily relies on, *Konkel v. Acuity*, 2009 WI App 132, 321 Wis. 2d 306, 775 N.W.2d 258, is distinguishable. Nancy Lynch injured Lisa Konkel in a motor vehicle accident. *Id.* at ¶ 3. Konkel received treatment for her injuries from Dr. Arvind Ahuja. *Id.* Acuity, Lynch's insurer, alleged that Ahuja's treatments were unnecessary and therefore sought to bring a subrogation claim against Ahuja for all damages Acuity incurred for that unnecessary treatment as well as any damages for pain and suffering awarded to Konkel related to that treatment. *Id.* at ¶ 6.

A divided court of appeals held that Acuity was barred from bringing a subrogation claim related to any allegedly unnecessary treatment Ahuja provided. A

party seeking subrogation attempts to stand in the shoes of the injured party. *Konkel*, 2009 WI App 132, ¶ 11. But because an unnecessary treatment is a form of medical malpractice, under Wis. Stat. Ch. 655, only the patient or a patient representative can bring an unnecessary treatment claim. *Id.* at ¶ 18. This, the majority of the court found, was consistent with the purpose behind Chapter 655 of limiting medical malpractice claims; if a tortfeasor's insurer was able to allege that the treatment that an injured party received was unnecessary, doctors would become routine defendants in personal injury cases. *Id.* at ¶ 32.

The dissent argued that the majority's holding was inconsistent with the companion purpose of Chapter 655—keeping medical costs down. *Konkel*, at ¶36 (Fine, J., concurring in part, dissenting in part). A physician treating a person injured as a result of the fault of another will have few reasons to avoid unnecessary treatment. The physician will be sure to get compensated for his services because the insurer cannot challenge the appropriateness of the treatment. Although a patient theoretically could pursue a malpractice suit against the physician for unnecessary treatment, she would have little incentive to do so. Her damages, including damages for pain and suffering associated with the treatment, would be compensated by the tortfeasor's insurer.

Unlike Acuity, Braun is not asserting a subrogation claim. It is not attempting to stand in Rivers's shoes to present a claim against her medical providers. It is not asserting a claim at all. It neither seeks damages against Rivers's medical providers nor

asks those medical providers to pay any portion of the damages it might be ordered to pay. Rather, as a defense Braun is asserting that Rivers's injuries were not caused by a defect in the design of its product but instead by the negligence of others. This theory of defense does not fall within the scope of Chapter 655 because it does not constitute a malpractice claim.

Rivers alternatively argues that Braun's proposed defense fails because, even if Braun could show that her medical providers were jointly negligent, she would still be entitled to recover the full amount of her damages from Braun. (ECF No. 66 at 5-6 (citing *Brown v. Hammermill Paper Co.*, 88 Wis. 2d 224, 232, 276 N.W.2d 709, 712-13 (1979)). Braun responds that Rivers's argument rests on an inaccurate, or at least incomplete, statement of Wisconsin law.

> In an action by any person to recover damages for injuries caused by a defective product based on a claim of strict liability, the fact finder shall first determine if the injured party has the right to recover damages. To do so, the fact finder shall determine what percentage of the total causal responsibility for the injury resulted from the contributory negligence of the injured person, what percentage resulted from the defective condition of the product, and what percentage resulted from the contributory negligence of any other person.

Wis. Stat. § 895.045(3)(a).

Thus, in its last clause, the statute permits what it refers to as "product defendants"—"the manufacturer, distributor, seller, or any other person responsible for placing the product in the stream of commerce," Wis. Stat. 895.045(3)(b)—to assert that "any other person" was responsible for the plaintiff's injuries, *see also* Wis. JI-Civl 3290;

3290.1. "The responsibility of a product defendant whose responsibility for the damages to the injured party is less than 51 percent of the total responsibility for the damages to the injured party is limited to that product defendant's percentage of responsibility for the damages to the injured party." Wis. Stat. 895.045(3)(d). In other words, a product defendant is liable for the whole of the plaintiff's damages only if its responsibility is at least 51 percent.

Braun's response and Rivers's reply verge off to discuss a variety of tangential issues, including whether Braun's plan to cast blame on Rivers's medical providers constitutes an affirmative defense, which side bears the burden of proof on the issue, and the sufficiency of the opinion of Braun's expert. The court declines to address these matters as they were not properly raised in Rivers's narrow motion for summary judgment. *See Griffin v. Bell*, 694 F.3d 817, 822 (7th Cir. 2012). As to the specific arguments presented in Rivers's initial brief in support of her motion for partial summary judgment, she has failed to show that any merits summary judgment in her favor. Accordingly, Rivers's motion for partial summary judgment ECF No. 56) will be denied.

4.3. Braun's Motion for Summary Judgment

Rivers has alleged claims of (1) negligence; (2) strict products liability – failure to warn; (3) strict products liability – design defect; (4) strict products liability – manufacturing defect; (5) breach of implied warranty of merchantability; (6) negligent

misrepresentation. (ECF No. 77-1 at 6-7.) In response to Braun's motion for summary judgment she has withdrawn her manufacturing defect and implied warranty claims. (ECF No. 77-1 at 7.) Braun seeks summary judgment as to the remainder of Rivers's claims. (ECF No. 65-30 at 9-10.)

4.3.1. Causation

Braun argues that Rivers cannot prove that her injuries were caused by the filter's lack of migration resistance. It contends that, because Muehrcke's opinions must be excluded, there is no evidence of causation. (ECF No. 65-30 at 17-19.)

As discussed above, the court rejects Braun's efforts to exclude Muehrcke's opinions as they relate to what caused the filter to migrate. Ultimately it will be up to the jury to decide what caused the filter to migrate, but Rivers has shown that Muehrcke reliably applied a differential etiology such that he may offer his causation opinion at trial. Because Rivers has presented evidence that could lead a reasonable finder of fact to conclude that the filter migrated because of a design defect, and that migration caused Rivers's injuries, this aspect of Braun's motion for summary judgment will be denied.

4.3.2. Failure to Warn

Braun argues that Rivers's failure to warn claim is barred by the learned intermediary doctrine. (ECF No. 65-30 at 20-21.) "The doctrine holds that the manufacturer of a prescription drug or medical device fulfills its duty to warn of the

product's risks by informing the prescribing physician of those risks." *In re: Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 751 (7th Cir. 2018).

Braun acknowledges that the Wisconsin Supreme Court has not addressed whether the doctrine exists in Wisconsin. Rivers argues that "[t]his Court should decline to apply the learned intermediary doctrine absent an express indication from the Wisconsin Supreme Court that the doctrine applies." (ECF No. 77-1 at 18-19.) But the absence of an express indication from the Wisconsin Supreme Court means only that this court must look to other sources in an attempt to determine whether the Wisconsin Supreme Court would adopt the learned intermediary doctrine. *See In re: Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d at 751.

In *In re: Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746 (7th Cir. 2018), the Court of Appeals for the Seventh Circuit held that "there is good reason to think that given the opportunity, the Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt the learned-intermediary doctrine for use in defective-warning cases like this one involving a surgical implant. We predict that the state high court would do so." *Id.* at 752. Rivers has not pointed to any subsequent authority suggesting that the Wisconsin Supreme Court, in fact, would not accept the learned intermediary doctrine. *Cf. Platten v. Smith & Nephew Inc.*, No. 20-C-1265, 2023 U.S. Dist. LEXIS 21029, at *24 (E.D. Wis. Feb. 7, 2023) (discussing *Zimmer* and stating

that "[t]his court is bound by that determination and will therefore proceed to apply that doctrine here"). Accordingly, the doctrine applies to Rivers's claim.

Rivers argues that Braun is not entitled to summary judgment on her failure to warn claim because its warnings were inadequate. Braun warned that implanting the "filter using an existing access site can result in incomplete filter deployment. This could in turn result in filter migration and/or inadequate protection against pulmonary embolism." (ECF No. 65-30 at 21.) It also warned that the filter should not be implanted into a vein greater than 28 millimeters in diameter. (ECF No. 65-30 at 21.) Finally, Braun warned of 13 other potential adverse effects, including "[e]mbolization of the device possibly resulting in cardiac arrythmia or compromise of cardiac valve function." (ECF No. 65-30 at 21.)

None of these warnings is relevant to the nature of Rivers's alleged injury. The filter was not implanted using an existing access site or into a vein of more than 28 millimeters in diameter. And embolization means only that the device may obstruct the vein; it does not necessarily warn of a risk of migration. Whether Braun's warnings were sufficient is a dispute the court cannot resolve on summary judgment.

Finally, Braun argues that Rivers's failure to warn claim fails because the alleged inadequacy of Braun's warnings did not cause her alleged injuries. (ECF No. 65-30 at 22-26.) "A product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by

the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). Braun contends that there is insufficient evidence that Rivers's doctors ever read Braun's warnings, there is no evidence that any other filter was available, and Rivers's doctors already knew that migration was a risk with any filter. In other words, even if Braun would have included the warnings that Rivers argues it should have included, she would have consented to receive a filter and her physician would implanted the same filter.

In response, Rivers asserts that, if Braun had provided additional warnings, her bariatric surgeon would have conveyed that information to her as part of the informed consent process. If she had been told that Braun's filter "had a tendency to migrate more in obese patients than nonobese patients or that there was a version of the VenaTech LP that had been designed to reduce the risk of migration, she would not have given consent to implantation of the VenaTech LP filter prior to her elective bariatric surgery." (ECF No. 77-1 at 22.) The citation that she offers in support of this assertion, PSOMF ¶25, does not support it. (ECF No. 95-1 at 6, ¶ 25 ("Upon successful implantation, Dr. Beres' expectation was that Ms. Rivers' VenaTech LP filter would remain in position and not migrate.").)

However, paragraph 21 of Rivers's proposed findings of fact states, "Had Ms. Rivers been informed that the VenaTech LP filter had a tendency to migrate more in

obese patients than nonobese patients or that there was a version of the VenaTech LP that had been designed to reduce the risk of migration, she would not have given consent to implantation of the filter prior to her elective bariatric procedure. Ex. 5, Declaration of Jeannine Rivers." (ECF No. 95-1 at 5.) This proposed finding of fact is supported by a citation to Rivers's declaration. (ECF No. 77-7.) That declaration, however, is unsigned, lacking either a scanned "wet signature" or an electronic signature in accordance with the court's electronic filing procedures, *see* ECF Policies and Procedures, II. C. 2., E.D. Wis., available at https://www.wied.uscourts.gov/e-filing/ecf-policies-and-procedures. Even though Braun, in response to Rivers's additional proposed findings of fact, noted that the declaration was unexecuted (ECF No. 104 at 16, ¶ 21), Rivers has failed to correct it.

As for Rivers's assertion that her physician "would have altered his informed consent procedure had the VenaTech LP warned about the increased risk of migration to obese patients or that there was a modified version of the filter that had been successfully designed to prevent migration" (ECF No. 77-1 at 21), she fails to point to any evidence in support. There is no indication that her physician testified that he would have passed along such information. Nor has Rivers pointed to the opinion of any expert that communication of such information was required for informed consent.

In the absence of evidence that additional warnings would have changed her physician's conduct, either by foregoing a filter, choosing a different filter, or conveying

additional information to Rivers (which then would have led to her refusing to consent to the procedure), Rivers cannot sustain a failure to warn claim. Accordingly, the court will grant Braun's motion for summary judgment as to that claim.

4.3.3. Design Defect

Braun argues that Rivers cannot sustain a design defect claim without Timmins's opinions. (ECF No. 65-30 at 26-28.)

Although the court has concluded that Timmins's opinions must be limited, he may largely offer his opinions that there were design defects in the filter that rendered it unreasonably dangerous. With respect to Timmins's opinion that the filter Braun sold outside the United States represented a safer alternative design, as explained above Rivers failed to sustain her burden to show that Timmins's finite element analysis was the product of a reliable methodology. However, other evidence—such as the real-world migration data—could lead a reasonable finder of fact to conclude that the filter sold outside the United States was a safer design. Whether that statistical variation was because the filter sold outside the United States was a safer design or because of some other reason will be a matter for the jury to decide.

4.3.4. Negligence

Rivers alleges that Braun was negligent in its "failure to exercise reasonable care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of" the filter. (ECF No. 77-1 at 27; *see also* ECF No. 1,

¶¶ 55-58.) Braun argues that it is entitled to summary judgment as to all of Rivers's theories of negligence. (ECF No. 65-30 at 30.)

In response, Rivers points to the arguments she made in support of her failure to warn and design defect claims. (ECF No. 77-1 at 27.) Thus, she implicitly concedes that her negligence claim is merely a parallel of these separate claims.

As a preliminary matter, the court must address whether such parallel claims are permitted under Wisconsin law. Neither party addresses the question. The only authority Rivers presents is *Bailey v. B. Braun Med.*, No. 1:16-CV-1544-LMM, 2021 U.S. Dist. LEXIS 210848, at *38 (N.D. Ga. Sep. 3, 2021), and she argues that, like the court in that case, her negligence claim should be allowed to proceed. The court in *Bailey*, however, explained how the plaintiff's negligence theories were viable under Georgia law. *Id.* at *38-*41.

Notwithstanding the parties' lack of argument, it is clear that Wisconsin permits a plaintiff to simultaneously pursue a statutory product liability claim and a common law negligence claim based on the same theory. *See* Wis. Stat. § 895.047(6); *Murphy v. Columbus McKinnon Corp.*, 2022 WI 109, ¶39, 405 Wis. 2d 157, 982 N.W.2d 898. As explained above, Rivers has presented evidence sufficient to sustain her claim that the design of the filter was defective. Consequently, she may pursue a parallel claim that this constituted common law negligence.

Rivers, however, cannot pursue a claim that Braun was negligent with respect to the warnings it provided. As explained above, Rivers has not presented evidence that different or additional warnings would have changed her physician's conduct or would have led to her refusing to consent to the procedure. For the same reasons, a parallel negligence claim fails for want of causation.

The only additional arguments she offers in support of her negligence claim are simply a few bald assertions. She asserts that Braun was negligent because it "failed to exercise reasonable care in that [it] chose never to seek clearance to market the safer design" in the United States. (ECF No. 77-1 at 27.) But she doesn't develop the argument. Whether to seek FDA approval to sell a medical device in the United States is undoubtedly a complex and multi-faceted consideration. And a company's decision to not seek FDA approval of a particular device, standing alone, is not enough to sustain a finding that the company was negligent.

Rivers also argues that Braun "failed to exercise reasonable care by downplaying the risks of migration in the VenaTech LP's IFU, particularly regarding risks in the obese population, and by failing to include any warning that the filter could become irretrievable by any other means than open heart surgery if it migrated to the heart." (ECF No. 77-1 at 27-28.) But that is simply a reiteration of her unsuccessful failure to warn claim, and it fails for the reasons discussed above. Accordingly, Braun's motion for summary judgment regarding Rivers's negligence claim will be denied as to Rivers's

theory that Braun was negligent for selling a product with a design defect but granted as to all other grounds.

4.3.5. Negligent Misrepresentation

Rivers alleges that Braun "negligently provided Plaintiff, Plaintiff's healthcare providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the Vena Tech filters; including, but not limited to, misrepresentations relating to the safety, efficacy, failure rate and approved uses of the Vena Tech LP filter." (ECF No. 1, ¶ 99.) She points to statements that "'[the Vena Tech LP filter was] the new standard in permanent vena caval filtration;' 'effective [for] clot trapping and preservation of caval patency;' and, the Vena Tech LP filter had 'unique, patented stabilizing legs and hooks to ensure self-centering and optimal positioning.'" (ECF No. 1, ¶ 100.)

Braun argues that this claim fails because there is no evidence that Rivers or any of her physicians ever saw or relied on any of these alleged misrepresentations. (ECF No. 65-30 at 33-34.)

In response, Rivers does not dispute Braun's assertion that there is no evidence that neither she nor her physicians saw or relied on any of Braun's alleged misrepresentations. Instead, she alleges that her misrepresentation claim is one of omission—that Braun failed to disclose certain pertinent details concerning the Vena Tech filters. (ECF No. 77-1 at 28.)

If Braun was silent about a defective condition in its filter, it may be liable for misrepresentation. *See In re Estate of Lecic*, 104 Wis. 2d 592, 604, 312 N.W.2d 773, 779 (1981) ("The general rule is that silence, a failure to disclose a fact, is not misrepresentation unless the nondisclosing party has a duty to disclose that fact."); *Platten*, 2023 U.S. Dist. LEXIS 21029, at *37 (quoting *Gracyalny v. Westinghouse Elec. Corp.*, 723 F.2d 1311, 1318 (7th Cir. 1983) ("A manufacturer has a duty to warn customers or users of defective conditions which may render its products unreasonably dangerous, as well as of any risks of injury that may be associated with its products.").

However, Rivers's misrepresentation claim is functionally her third iteration of her failure to warn claim. Rivers has failed to produce evidence from which a reasonable finder of fact could conclude that Rivers's or her doctors' conduct would have changed if Braun had included in its warnings the information that Rivers argues it should have disclosed. In other words, even if Braun had disclosed the information that Rivers argues was required, she presents no evidence that she would have received a different filter or avoided the complications she suffered. Because Rivers has failed to present evidence that would establish the requisite element of a "causal link between the conduct and the injury," *Hatleberg v. Norwest Bank Wis.*, 2005 WI 109, ¶40, 283 Wis. 2d 234, 700 N.W.2d 15, the court will grant Braun's motion for summary judgment as to Rivers's misrepresentation claim.

4.3.6. Punitive Damages

Although Rivers alleged "Punitive Damages" as the "Seventh Cause of Action" in her complaint (ECF No. 1 at 24), she now states that she "is not asserting punitive damages as a separate cause of action." (ECF No. 77-1 at 31.) Instead, punitive damages are merely a form of relief that she seeks.

"The plaintiff may receive punitive damages if evidence is submitted showing that the defendant acted maliciously toward the plaintiff or in an intentional disregard of the rights of the plaintiff." Wis. Stat. § 895.043(3). The plaintiff must sustain her demand for punitive damages by clear and convincing evidence. *Strenke v. Hogner*, 2005 WI 25, ¶40, 279 Wis. 2d 52, 694 N.W.2d 296. In the context of a product liability case, the conduct need not be directed toward the plaintiff personally; it is sufficient "that the harm suffered was the result of the manufacturer's reckless disregard for the safety of product users, consumers or others who might be harmed by the product." *Id.* at ¶ 49 (quoting *Sharp v. Case Corp.*, 227 Wis. 2d 1, 21, 595 N.W.2d 380, 389 (1999)).

Braun argues that Rivers is not entitled to punitive damages because there is no evidence to support them. (ECF No. 65-30 at 34-35.) It argues that Rivers cannot prove by clear and convincing evidence that it acted with malice or intentional disregard because:

> (1) the FDA cleared the VenaTech LP pursuant to its 510(k) review; (2) B. Braun complied with FDA requirements and industry standards in designing and developing the VenaTech LP; (3) the clincial [sic] data for the twenty years the VenaTech LP has been on the market demosntrates

> [sic] its safety and efficacy; and (4) the VenaTech LP labeling warns of migration, the precise risk at issue.

(ECF No. 65-30 at 35.)

In response, Rivers argues that, notwithstanding the 510(k) review, Braun's decision to continue to sell the filter when it knew of migration risks and the availability of a safer filter could support a finding that it intentionally disregarded the rights of patients. (ECF No. 77-1 at 31-34.)

At this stage it is Braun's burden to show that no reasonable jury could award Rivers punitive damages on her remaining claims. It has failed to do so. For the reasons cited by Rivers, a reasonable finder of fact could conclude that punitive damages are appropriate. Therefore, the motion for summary judgment as to Rivers's demand for punitive damages will be denied. That does not mean that the court is finding that it will be appropriate to send a punitive damages question to the jury. That is a decision the court can make only after the close of the plaintiff's case at trial.

5. Conclusion

IT IS THEREFORE ORDERED that Jeannine Janet Rivers's "Motion for Partial Summary Judgment on Certain Affirmative Defenses" (ECF No. 56) is **denied**.

IT IS FURTHER ORDERED that B Braun Interventional Systems Inc. and B Braun Medical's "Motion to Exclude the Opinions of Rebecca Betensky, Ph.D." (ECF No. 57) is **denied**.

IT IS FURTHER ORDERED that B Braun Interventional Systems Inc. and B Braun Medical's "Motion to Exclude or Limit the Opinions of Jennifer Cook, MD, FAHA, FACC" (ECF No. 59) is **granted in part and denied in part** as set forth in this decision.

IT IS FURTHER ORDERED that B Braun Interventional Systems Inc. and B Braun Medical's "Motion to Exclude or Limit the Opinions of Leigh Anne Levy, RN" (ECF No. 60) is **granted in part and denied in part** as set forth in this decision.

IT IS FURTHER ORDERED that B Braun Interventional Systems Inc. and B Braun Medical's "Motion to Exclude the Opinions of Ross DeVere, Ph.D." (ECF No. 61) is **granted**.

IT IS FURTHER ORDERED that B Braun Interventional Systems Inc. and B Braun Medical's "Motion to Exclude the Opinions of Lucas Timmins, Ph.D." (ECF No. 62) is **granted in part and denied in part** as set forth in this decision.

IT IS FURTHER ORDERED that B Braun Interventional Systems Inc. and B Braun Medical's "Motion to Exclude the Opinions of Derek Muehrcke, M.D." (ECF No. 63) is **granted in part and denied in part** as set forth in this decision.

IT IS FURTHER ORDERED that B Braun Interventional Systems Inc. and B Braun Medical's "Motion for Summary Judgment" (ECF No. 65) is **granted in part and denied in part**. The motion is granted as unopposed as to Rivers's strict products liability – manufacturing defect and breach of implied warranty of merchantability

claims. The motion is granted as to Rivers's strict products liability – failure to warn and negligent misrepresentation claims. The motion is granted in part with respect to Rivers's negligence claim as set forth in this decision. The motion is denied with respect Rivers's strict products liability – design defect claim.

Dated at Milwaukee, Wisconsin this 31st day of October, 2023.

WILLIAM E. DUFFIN
U.S. Magistrate Judge